

### **REMARKS**

Claims 1-27 are pending in the application. Claims 1-27 are rejected. Claims 1, 13, and 27 are presently amended. Further, a Declaration of Gilbert R. Gonzales under 37 C.F.R. § 1.132 is submitted with this response. In view of the amendments, the Declaration, and the discussion below, Applicant respectfully submits that the rejections of the claims have been overcome.

### **The Invention of the Present Application**

The effective administration of medications for the treatment of disease symptoms and for the alleviation of pain, i.e., pain management, is an important aspect to the overall treatment of patients for both curable diseases and terminal illnesses. Oral administration has been widely used for dispensing pain medications such as narcotic and non-narcotic analgesics. However, oral administration is oftentimes not possible due either to obstruction of the oral and gastrointestinal tract or to severe nausea. Further, parenteral administration, including intravenous administration (e.g., IV drips), has been used for long-term administration of medication in controlled dosages. However, parenteral administration is invasive and usually painful to the patient. Further, parenteral administration is also not practical for long-term patient care because terminally ill patients may not have the physical capability of performing the injection procedure, and if physically able, may not have the knowledge to properly

choose an injection site. Thus, multiple appointments with medical personnel are required.

Thus, rectal administration of medications has become widely used for administering a number of different medications in order to overcome the drawbacks of oral and parenteral/intravenous administration. In this method, medications are absorbed through the rectal mucous membranes. However, there are drawbacks with this type of administration, as well, and thus there is need for further improvement for methods of pain management.

These drawbacks have been overcome by the invention of the present application, which includes an infusor system for administering medications to a patient through an indwelling venous needle or venous catheter. This needle or catheter is placed into a superficial vein or veins of the pelvic or inguinal region. A supply of medication is delivered into a tube, and from the tube into the IV needle or indwelling catheter. This system eliminates the large expenses associated with the above-described procedures, which involve administration and continual monitoring by professional medical personnel. The medications dispensed through the infusor system are rapidly and efficiently absorbed into the necessary areas of the body for alleviation of the medical condition or the pain associated therewith.

Further, medications can be delivered into the intraspinal regions through an indwelling needle or catheter. As medication is dispensed, intraabdominal pressure

is increased, such as by utilizing an abdominal restraint or binder. The blood flow in the vertebral venous plexus is reversed, and the dispensed medication is delivered from the rectal veins directly into the vertebral bones, the epidural and intrathecal space, and the spinal cord.

Therefore, the infusor system of the present invention provides a more direct infusion of medication, either continuously or in bolus dosages, into the spinal cord and other vertebral structures as compared to previous oral, parenteral, or rectal administration, for more effective pain management.

#### **Double Patenting Rejections**

The Examiner has rejected claims 1-27 on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over claims 1-22 of U.S. Patent No. 5,846,216 (Gonzales) in view of U.S. Publication No. 2001/0049486 (Evans). The Examiner states that although Gonzales does not explicitly recite a delivery component or the use with venous blood vessels, Evans does teach delivering medications to a venous blood vessel. Therefore, the Examiner states that it would have been obvious to one skilled in the art, at the time of the invention, to use the teachings of Gonzales and Evans to reach the present invention. Applicant respectfully disagrees. Applicant further notes that the Examiner also uses the combination of Gonzales and Evans in rejecting many of the claims as obvious under 35 U.S.C. § 103 (including independent claims 1 and 27). Thus, Applicant will deal with the obviousness

of the claims, both for double patenting and for Section 103, below in the discussion of the rejections under 35 U.S.C. § 103.

**Claim Rejections 35 U.S.C. § 103**

The Examiner has rejected each of pending claims 1-27 under 35 U.S.C. § 103(a) as being unpatentable over Gonzales in view of one or more other references. First, the Examiner has rejected claims 1, 23, and 27 as being unpatentable over Gonzales in view of Evans. The Examiner states that claims 1, 23, and 27 differ from Gonzales in disclosing the administration of medication through venous means. The Examiner goes on to state that Evans discloses administration of medication through venous means and concludes that it would have been obvious at the time of the invention to one of ordinary skill in the art to administer the medication, as in Gonzales, through a venous blood vessel, as in Evans, to improve the function.

Second, claims 2, 3, and 8 are rejected as unpatentable over Gonzales in view of U.S. Patent No. 5,061,243 (Winchell). The Examiner states that the claims differ from Gonzales in disclosing the delivery component with the venous needle, venous blood vessel, and the particular medication. However, the Examiner states that Winchell teaches a venous needle, and concludes that it would have been obvious to use the venous needle and medication with Gonzales in such a manner as in the claims.

Third, claims 5-7 and 22 have been rejected as being unpatentable over Evans in view of Gonzales. The Examiner states that claims 5-7 differ from Evans in disclosing liquid medication, or a valve allowing flow. The Examiner states that Gonzales teaches liquid medication and a valve allowing flow, and that it would have been obvious to deliver liquid medication through a venous blood vessel in such a manner in order to improve function.

Fourth, claims 9-12 and 18-21 are rejected as unpatentable over Evans in view of Gonzales. The Examiner states that these claims differ from Evans in disclosing increased intraabdominal pressure, but that it would have been obvious to use an abdominal binder or restraint, as shown in Gonzales, in such manner to improve function.

Fifth, claims 13-15 are rejected as unpatentable over Gonzales in view of U.S. Publication No. 2002/0188253 A1 (Gordon). The Examiner states that the claims differ from Gonzales in disclosing the method of administering medication, including the initiation of flow of medication at the injection site from a syringe to a tube. The Examiner concludes that such is shown by Gordon, and that it would have been obvious to administer medication in such a manner.

Sixth, claims 16 and 17 are rejected as unpatentable over Evans in view of Gonzales. The Examiner states that the claims differ from Evans in disclosing an IV

bag with a connecting pump, but that such is disclosed by Gonzales, and that it therefore would have been obvious to use such an IV bag and pump.

And seventh, claims 24-26 are rejected as unpatentable over Evans in view of Gonzales. The Examiner states that the claims differ from Evans in disclosing the spinal region of the body as the site where liquid medication is delivered, but concludes that Gonzales teaches the spinal region as the delivery site, and that it would have been obvious to use the spinal region in such a manner.

Thus, in rejecting each of claims 1-27 of the application as obvious, the Examiner has used the Gonzales reference in combination with at least one other reference. And, in particular, independent claims 1, 13, and 27 have been rejected as obvious either over Gonzales in view of Evans (claims 1 and 27) or over Gonzales in view of Gordon (claim 13).

In response, Applicant first notes that independent claim 1, as presently amended, recites that the delivery component (i.e., the needle or catheter) is placed in confronting relationship with a venous blood vessel, and further recites that this venous blood vessel is chosen from "a pudic vein, an internal pudic vein, and an external pudic vein." By placing the needle and/or catheter in confrontation with one of this family of pudic veins, the apparatus of the present application can use the reversal of blood flow in the vertebral venous system (Batson's Plexus) to directly and intravenously administer medication to the intraspinal region of a patient. As will be described in

greater detail below, such administration via the family of pudic veins would not have been obvious to those of skill in the art in view of the knowledge of rectal administration provided by Gonzales (which represents the state of the art in delivering intraspinal medication by reversal of blood flow in Batson's Plexus prior to the present invention). Further, such administration, by the system of the claimed invention, provides advantages not previously obtained. Thus, Applicant submits that the present claims are not obvious over Gonzales in combination with either Evans or Gordon.

As noted by the Examiner, Gonzales describes a system for rectal administration of medication into a patient body. Medication is dispensed through a delivery tube and to a dispenser head positioned in the rectum of a patient. When delivered rectally, as in Gonzales, medication must be transported across the rectal mucous membranes and then into the patient's vasculature. (See the attached Declaration of Gilbert R. Gonzales). The rectal mucous membranes prevent the passage of large molecular drugs, and thus only a certain limited number of drugs can cross the rectal mucous membranes.

In the present application, a system is disclosed for administering medications by catheterization (or use of a needle or other delivery component) of the pudic vein, the internal pudic vein, or the external pudic vein. Thus, medication can now be directly administered to a patient's intraspinal area via veins that directly communicate with Batson's Plexus (to the exclusion of cross-communication with any

other vascular region). However, until the claimed invention of the present application, drugs were not administered intravenously to be directed to the intraspinal region by increasing intraabdominal pressure to cause reversal of blood flow in Batson's Plexus. (See attached Declaration of Gilbert R. Gonzales). And, until the present invention, rectal administration was the only sort of administration of drugs that was successfully used to direct drugs into the bloodstream to thereafter be subjected to reversal of blood flow in Batson's Plexus. Thus, while Applicant acknowledges that needles and catheters are well known tools of intravenous administration, and rectal dispenser heads are well known tools of rectal administration, a system including a delivery component in confronting relationship with a pudic vein (in the claimed system) was not well known, and would not have been obvious.

For example, there are several advantages which obtain from catheterization of one of the family of pudic veins as in the present invention, as recited in claims 1, 13, and 27 (and as discussed in the attached Declaration of Gilbert R. Gonzales). None of these advantages can be obtained via rectal administration. For example, pudic vein catheterization allows for the patient to be upright and ambulatory during the dispensing of medication. This contrasts with the rectal dispenser head mucous membrane infusion of Gonzales, wherein a patient must remain recumbent during the dispensing of medication. Further, previous drugs that could not be infused rectally (for example, those with structure too large to cross the rectal mucous



membranes) can now be administered by pudic vein delivery. Further, massive drug deliveries can be given through catheterization of the pudic vein. The rectal dispenser head mucous membrane infusion method exhibits an across-the-membrane rate limiting effect, which requires relatively potent drugs to be delivered (due to the relatively low volume per time of infusion). However, through a system including IV pudic vein delivery, which is now possible due by the present invention, one can deliver high volumes of low potency drugs. And further, because the pudic veins directly communicate with Batson's Plexus (to the exclusion of any cross-communication with other vessels), medications may be delivered directly to Batson's Plexus without the medication being diluted by diversion to other vessels. In the previous rectal dispenser head mucous membrane infusion of Gonzales, drugs could not be focused to particular veins (such as the pudic veins), and thus would also enter vessels having cross-communication with other vessels of the body. Thus, delivery of medication in rectal dispenser head mucous membrane infusion is more dilute and less effective. Applicant submits that given all these advantages, if pudic vein catheterization, and thus IV delivery of medication to the intraspinal region via reversal of blood flow in Batson's Plexus were obvious, it certainly would have been done previously. As it was not done, Applicant submits the claimed system was not obvious over Gonzales in view of either Evans or Gordon.

In view of the above, Applicant submits that the rejection of independent claims 1 and 27 as obvious over Gonzales in view of Evans is in error and should be withdrawn. Applicant further submits that the rejection of independent claim 13 over Gonzales in view of Gordon is in error and should be withdrawn. And thus, Applicant further submits that the rejection of all of their dependent claims is in error and should be withdrawn. Further, Applicant submits that the rejection for obviousness-type double patenting should be withdrawn.

### **Conclusion**

For the foregoing reasons, it is submitted that all claims are patentable, and a Notice of Allowance is respectfully requested.

No fee is believed due as a result of this Response. Any deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,  
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